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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,911	11/06/2000	John Hermon-Taylor	117-323	7604
23117	7590	10/21/2003	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/705,911

Applicant(s)

HERMON-TAYLOR ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24, 26 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24 and 48-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 24, 26 and 48-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The amendment and response filed on 8-1-2003 are acknowledged. Claims 24 and 26 have been amended. Claims 25 and 27-47 have been canceled. Claims 48-52 have been added. This application contains claim 26 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 24 and 48-52 are currently under examination.

Information Disclosure Statement

The PTO-1449 form filed 7-12-2001 is still missing. It was requested that Applicant furnish a copy of said form so the cited references can be considered. However, Applicant submitted copies of references and not the PTO-1449 form itself. Consequently, the aforementioned references were not considered.

Claim Objections Withdrawn

The objection to claim 26 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claim 25 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides having a sequence comprising SEQ ID NO:24, does not

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reasonably provide enablement for the myriads of other polypeptides species claimed is withdrawn.

Cancellation of said claim has rendered the rejection moot.

The rejection of claim 25 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 24-25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “administering an effective amount of” is withdrawn in light of the amendment thereto and the cancellation of claim 25.

The rejection of claims 24-25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase “which method comprises” is withdrawn in light of the amendment thereto and the cancellation of claim 25

The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “epitope” is withdrawn. Cancellation of said claim has rendered the rejection moot.

Claim Rejections Maintained and New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The rejection of claim 24 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides having a sequence comprising SEQ ID NO:24 and portions of said polypeptide that induce a specific immune response against a mycobacterium, does not reasonably provide enablement for the myriads of other polypeptides fragments claimed is maintained for the reasons of record.

Applicant argues:

1. Claim 24 does not require any function of the variant polypeptides. Said variants merely need to be sufficiently similar to the polypeptide of SEQ ID NO:24 that the immune response to said variant polypeptide would also be effective against the mycobacterium.
2. It would be straightforward for one of ordinary skill in the art to determine whether administration of a particular polypeptide successfully raises a suitable immune response.

Applicant's arguments have been fully considered and deemed non-persuasive. The rejected claims still recites fragments of the polypeptide encoded by SEQ ID NO:24 without the requirement of inducing a specific immune response against a mycobacterium. While the amendment to claim 24 was sufficient to overcome the rejection as it applies to parts (ii) and (iii) of claim 24, it was sufficient to overcome the rejection as it applies to part (iv). Said portion of the claim recites the limitation of "a fragment of a polypeptide of (i) comprising at least 12 amino acids and an "epitope". Since the sequences of said "epitopes" are not set forth in specification and one of skill in the art would not be able to discern what portions of SEQ ID NO: 24 encode said epitopes, one of skill in the art would not be able to make the claimed invention. Hence the specification with regard to part (iv) of claim 24 is not enabling.

The rejection of claim 25 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record.

Applicant argues:

1. The variants claimed are all defined specifically in relation to their amino acid sequence and hence the specification does provide a "precise definition as by structure, formula, chemical name or physical properties".
2. The invention does not relate to polypeptides *per se* but the ability of said polypeptides to induce an immune response against mycobacterium.
3. The variants listed in claim 24 have the same effect in the claimed method as the polypeptide according to SEQ ID NO:24 itself since the variants have to be sufficiently similar SEQ ID NO:24 to be able to produce an immune response that is active against the polypeptide of SEQ ID NO:24 and therefore the mycobacterium.
4. Fiddes v. Baird (30 USPQ 2d 1481, 1483) does not apply to the instant claims since the variant peptides claimed are defined specifically in relation to the amino acid sequence of SEQ ID NO:24 and as such a person of ordinary skill could clearly derive variant sequences falling within the scope of claim 24 part (ii), part (iii) and part (iv) from SEQ ID NO:24 given the application with little or no further experimentation.

Applicant's arguments have been fully considered and deemed non-persuasive. The rejected claims still recites fragments of the polypeptide encoded by SEQ ID NO:24 without the requirement of inducing a specific immune response against a mycobacterium. While the amendment to claim 24

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was sufficient to overcome the rejection as it applies to parts (ii) and (iii) of claim 24, it was not sufficient to overcome the rejection as it applies to part (iv). Said portion of the claim recites the limitation of “a fragment of a polypeptide of (i) comprising at least 12 amino acids and an “epitope”. Since the sequences of said “epitopes” are not set forth in specification and one of skill in the art would not be able to discern what portions of SEQ ID NO: 24 encode said epitopes, the specification does not satisfy the written description requirement under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 48-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term “epitope” is maintained for reasons of record.

Applicant argues:

1. Said term would be clear to one of skill in the art.
2. The term is clearly defined on page 16, lines 17-36 of the specification.
3. Claim 24 relates to a method of raising an immune response and therefor would obviously relate to an epitope that may be used in raising said immune response.

Applicant's arguments have been fully considered and deemed to be non-persuasive.

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The passage of the specification cited by Applicant, contrary to Applicant's assertion, does not explicitly define the term "epitope". Page 16, lines 16-36 discusses "an epitope which is specific to the **pathogenicity** of the mycobacterial cell from which it is derived" which is contrary to Applicant's assertion that one of skill in the art would interpret said term to mean immuno-epitopes. Epitopes specific for the pathogenicity of the mycobacterial are not necessarily immuno-epitopes. Consequently, the rejection under 35 U.S.C. 112, second paragraph, is warranted.

Claims 48-52 are vague and indefinite since they are dependent on rejected claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
October 16, 2003